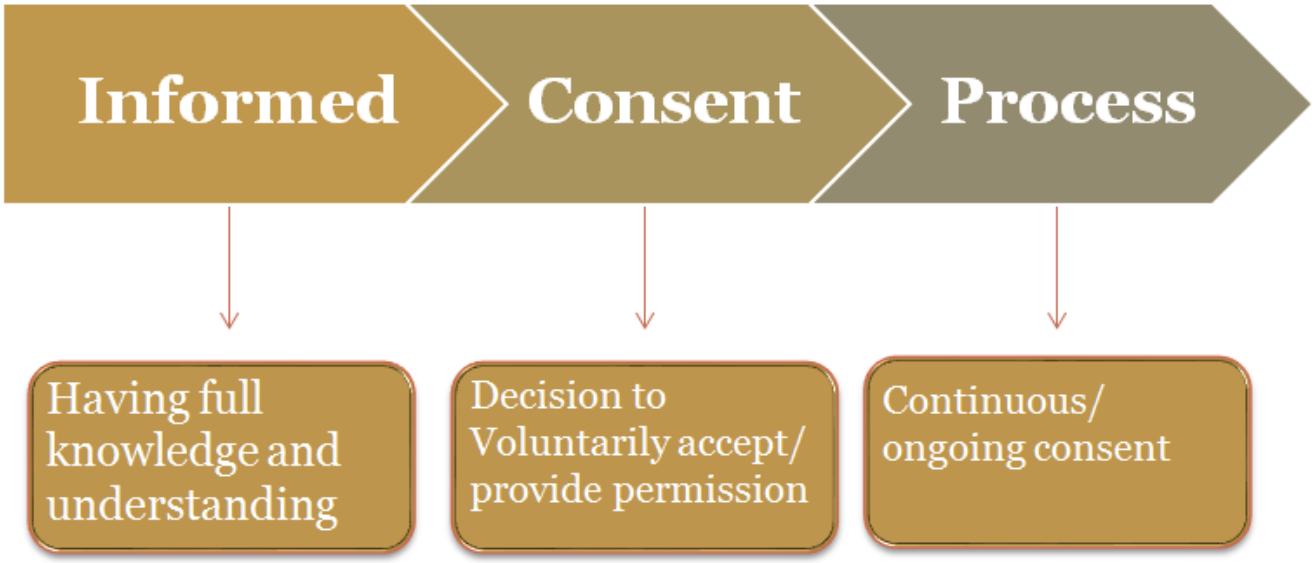
Regional Health

Informed Consent Guidance



RH IRB
Guidance
v.2019

Informed consent provides participants with sufficiently detailed information on the study so that they can make an informed, voluntary and rational decision to participate.

Background

The concept of informed consent is rooted in two important historical documents: The Nuremberg Code and The Belmont Report. The Nuremberg Code, which came about as a result of the Nazi War Crimes Tribunal, was the first internationally recognized code of research ethics and provided the foundation for regulations to protect human research subjects in the United States. In recognition of the importance of informed consent, "The voluntary consent of the human subject is absolutely essential", was listed as the primary tenet of the Nuremberg Code.

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines that should be followed to ensure that such research is conducted in accordance with those principles. The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement: *respect of persons, beneficence* and *justice*. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, IRB reviewers and interested citizens in understanding the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

Informed consent is one of the primary ethical requirements underpinning research with human subjects; it reflects the basic principle of respect for persons. It is too often forgotten that informed consent is an ongoing process, not a piece of paper or a discrete moment in time. Informed consent assures that prospective human subjects will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. This assurance protects all parties: both the subject, whose autonomy is respected, and the investigator, who otherwise faces legal hazards.

Definition

Informed consent is a process that includes the presentation of information to the prospective subject, adequate opportunity for the subject to ask questions and have them answered, and documentation of the voluntary decision to participate. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

Requirements for informed consent are contained within Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46), which is the primary federal statute pertaining to the protection of human subjects in research that is conducted using federal funds. Regional Health (RH) Institutional Review Board (IRB) maintains a Federal-wide Assurance (FWA00003686) with the federal Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP), which extends the federal regulations to all research conducted by individuals who are affiliated with the Regional Health Network, regardless of the source or lack of funding.

The Consent Process

The consent process is the beginning of informed consent. The key elements of the consent process include:

- Full disclosure of the nature of the research and the subject’s participation
- Facilitate understanding on the part of the potential subjects
- The subject’s voluntary choice to participate

Required Elements of Informed Consent

Unless specifically waived by the IRB, use the following checklist to ensure the consent form has all required elements in each consent form:

General Elements of the Informed Consent (45 CFR 46.116)	✓
• The information that is given to the subject or the legally authorized representative shall be in language understandable to the subject or the legally authorized representative. • The prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. • Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research • This part of the informed consent must be organized and presented in a way that facilitates comprehension. • Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts; • Facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. • No informed consent may include any exculpatory language through which the subject or the legally authorized representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence • If FDA regulated, the statement: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."	

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Informed Consent Elements (45 CFR 46.116) - the follow questions will address the basic elements of informed consent.	✓
b1 - Is there a statement that the study: • Involves research; • An explanation of the purposes of the research; • The expected duration of the subject's participation • And, identification of any procedures which are experimental. For an Initial Review ALL the above must be found.	
b2 - Is there a description of any reasonably foreseeable risks or discomforts to the subject?	
b3 - Is three a description of any benefits to the subject or to others which may reasonably be expected from the research?	
b4 - Is there a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject?	
b5 - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;	
b6 - For research involving more than minimal risk, is there an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained?	
b7 - An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;	
b8 - A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.	
b9 - One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens: (i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or	

biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or (ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.	

Additional Elements	✓
c1. Statement that the particular treatment or procedure may involve risks to the subject (embryo or fetus, if subject is, or may become, pregnant).	
c2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	
c3. Any additional costs to the subject that may result from participation in the research.	
c4. Consequences of a subjects decision to withdraw from the research and procedures for orderly termination of participation by the subject.	
c5. Statement that significant new findings developed during the course of the research, which may related to the subject's willingness to continue participation, will be provided to the subject.	
c6. Approximate number of subjects involved in the study.	
c7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;	
c8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and	
c9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).	

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HIPAA Authorization Elements (45 CFR 164)	✓
1 - Does the HIPAA Authorization have the following elements? If no, list the element(s) which need to be send back to the PI to add to the form: 1. Description of the information to be used or disclosed 2. Names or identification of individuals authorized to use receive, or disclose information 3. Description of each purpose 4. Expiration date 5. Individual signature and date 6. A statement that the individual has the right to revoke the authorization in writing, and either: *The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or Reference to Regional Health's notice of privacy practices.*	
2 - If the study has unconditional components, are they easily identified, and understandable, for a participant to opt-in? If no, please explain. *A statement notifying the individual of the ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization. HIPAA allows Regional Health to combine conditional and unconditional components of research into a single form. However, the authorization must clearly differentiate between conditioned and unconditioned components and subjects must be given the option to participate or "opt in" to the unconditioned research activities. If the research involves the use of psychotherapy notes, the authorization can only be combined with another authorization for the use/disclosure of psychotherapy notes.* ◦ **Conditional components** refer to those components in which the participant must sign an authorization for use/disclosure of PHI in order to participate in the research study. ◦ **Unconditional components** refer to those components in which the participant is not required to participate (e.g. sub-study or secondary research) in order to participate in the main research study;	
In reviewing future research components and determining if the information sufficient, you may wish to consider following: ◦ The sophistication of the patient/research population ◦ Nature of the primary study ◦ Is there any coercive aspect associated with participating in the future research component? ◦ Age (special consideration given for children?) ◦ The health condition of the patient population or the nature of their illness ◦ Sensitivity of information being collected ◦ Nature/extent of identifiable PHI ◦ Whether the research involves bio-specimens or only data ◦ Whether the research data will remain within the covered entity or be disclosed to an	

outside party, a ◦ Expiration Date/Event (timeframe in which the PHI can be used).	
3 - If there a request to use PHI for future research, is it understandable, and is there a place for the participant to sign if they choose to allow use of their PHI for future research? ◦ Authorizations need not be study specific where they pertain to future research. A request to use PHI for future studies may be generalized and not study specific in recognition of the fact it may not be possible to fully describe such studies in detail due to their prospective nature. Authorizations for future research must adequately describe future research purposes to the extent that it would be reasonable for the individual to expect that his/her PHI could be used or disclosed for future research. ◦ A statement notifying the individual of the potential for the information disclosed pursuant to the authorization, to be subject to re-disclosure by the recipient (i.e. once the information is released outside Regional Health there is no longer a guarantee of confidentiality).	

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Informed Consent Form Stamps

Regional Health IRB policy requires that approved consent forms, advertisements, recruitment notices, etc. provided to subjects display one of the following:

1. The IRB Approval stamp, indicating the date of approval for the protocol, OR;
2. The following statement: "*This informed consent form* [substitute advertisement or applicable term] *and research protocol was approved by the Regional Health Institutional Review Board for the Protection of Human Subjects on* [Date of approval], *and expires on* [date of expiry]."

Waiver of Informed Consent Documentation

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects.

IMPORTANT: A Waiver of Consent Documentation is not a waiver to skip the whole consent process!!!

A waiver of documentation of informed consent is requested when a signed consent document is not required (i.e., verbal or implied consent). Consent will still be obtained from participants; however, they will not be required to sign the consent form.

There are only two circumstances when the IRB may waive the requirement to obtain a signed consent form:

1. The only record linking the research participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality (participant must be asked if he/she wants a copy of the documentation)

   OR

2. The research presents no more than minimal risk of harm to participants and involves no procedure for which written consent is normally required outside of the research context (e.g., no risk surveys or interviews)

For example, if you are conducting an online survey and the survey does not ask for any identifiable information. The consent form would need to contain a statement indicating that completing the survey implies consent to participate in the research.